

REMARKS

Claims 72-95 were pending at the time of mailing the Final Office Action. In the Final Office Action, the Examiner withdrew claims 73-83 and 85-95 from consideration, and rejected claims 72 and 84. Applicants presently amend claims 72 and 84 for clarification of certain features to expedite allowance of the present application. The present amendments do not add any new matter. Additionally, Applicants presently cancel claims 76-83 and 88-95 for inclusion in a divisional application. Upon entry of the amendments, claims 72-75 and 84-87 remain pending in the present application and are believed to be in condition for allowance.

Election/Restrictions

Applicants respectfully traverse the Examiner's withdrawal of dependent claims 73-75 and 85-87 from consideration. Applicants stress that claims 73-75 and 85-87 depend from claims 72 and 84, respectively. Accordingly, the restriction of claims 73-75 and 85-87 based on the absence of a generic or linking claim does not make sense and should be withdrawn. However, if the Examiner chooses to maintain the restriction, Applicants note that upon allowance of their respective base claims (claims 72 and 84), dependent claims 73-75 and 85-87 should also be allowed.

Rejections under 35. U.S.C. § 101

The Examiner rejected claims 72 and 84 under 35 U.S.C. § 101 “because the claimed invention is directed to non-statutory subject matter.” Final Office Action, page 2.

Specifically, the Examiner stated:

The claim does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically it does not appear to produce a tangible result because emitting and detecting light necessary to measure the blood oxygen saturation is nothing more than data gathering as a precursor for mathematical processing based upon a law of nature (the steps of which are not set forth). The claim fails to use or make available for use the result of the determination to enable its functionality and usefulness to be realized. A practical application is not explicitly recited in the claims nor does it flow inherently therefrom.

Final Office Action, page 2.

Applicants presently amend claim 72 to recite “calculating a blood oxygen saturation reading based on the plurality of detected light spectrums.” Similarly, Applicants amend claim 84 to recite “calculating a blood oxygen saturation reading based on the detected first light and the detected second light.” As such, Applicants respectfully submit that amended claims 72 and 84 fully comply with 35 U.S.C. § 101. Therefore, Applicants respectfully request withdrawal of the rejection of independent claims 72 and 84 under 35 U.S.C. §101. Further, Applicants request an indication of allowance for claims 72 and 84 and the claims depending therefrom.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 72 and 84 under 35 U.S.C. § 103(a) as being obvious over Lewis et al. (U.S. Patent No. 5,902,235, hereinafter “Lewis”) in view of Baker et al. (U.S. Patent No. 5,431,159, hereinafter “Baker”). Specifically, the Examiner stated:

Lewis et al. teach an oximeter that emits and detects light at measurement wavelengths including 735 nm and a reference wavelength at 805 nm (a known isobestic point for oximetry measurements). Thus, Lewis et al. teach all of the features of the claimed invention except that light between 880 and 940 nm is emitted and detected. Baker et al. teach 880 nm light is a suitable wavelength for performing the isobestic measurement in an oximeter arrangement (column 7, lines 61 – 66). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lewis et al. to measure at 880 nm instead of 805 nm, since Baker et al. teach that this is an alternate wavelength to perform an isobestic measurement in an oximeter, and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

Final Office Action, page 3.

Applicants traverse the Examiner’s rejection under 35 U.S.C. § 103(a). The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (P.T.O. Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of

reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. & Inter. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. § 2145.

Applicants respectfully assert that the theoretical combination of Lewis and Baker suggested by the Examiner is precluded because the references *teach away* from each other. Indeed, Baker is directed to non-invasive pulse oximeters and Lewis explicitly teaches away from such pulse oximeters. Further, Baker relates to measuring pulsative characteristics and Lewis relates to measuring venous characteristics. Applicants respectfully remind the Examiner that when considering these arguments, the Examiner should recall that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Applicants assert that Baker is directed to pulse oximetry and that Lewis teaches away from pulse oximetry. Support for this assertion can easily be found in the respective references. For example, the following statement from the "Field of the Invention" section of Baker clearly indicates that Baker relates to pulse oximeters:

This invention relates to non-invasive oximetry of the pulse type in which light, which has irradiated a volume of arterial blood within a subject, is sensed in order to determine oxygen saturation of the subject's blood.

Baker et al. col. 1, lines 9-12 (emphasis added).

Lewis, on the other hand, clearly indicates that combining the invention described by Lewis with a pulse oximeter, such as that described by Baker, would be inappropriate. For example, Lewis states the following:

[A]rterial pulse oximeter and blood pressure monitors, etc., ... do not provide accurate, ongoing, timely (instantaneous) information as to cerebral (brain) blood oxygenation state, particularly since the brain blood supply is extensive, diffuse, pervasive, and largely venous rather than arterial. Of course, it is also thus devoid of conventional pulsative characteristics essential to the operation of conventional oximeters.

Accordingly, such devices are not appropriate for cerebral usage, and of course they are typically made to be applied only to peripheral tissue or appendages in any event, i.e., a finger or ear lobe, and are not utilized in conjunction with venous blood.

Lewis et al., col. 2, lines 44-58 (emphasis added).

As clearly demonstrated by the quoted passage above, Lewis teaches away from monitors that utilize pulsative characteristics. Indeed, Lewis explicitly lists oximeters that utilize pulsative characteristics as among the devices that are *not* appropriate for the functions and purposes of the invention set forth by Lewis. Thus,

the pulse oximeter described by Baker is clearly within the group of devices that Lewis teaches away from. Accordingly, Applicants assert that the theoretical combination of Lewis and Baker, as suggested by the Examiner, is completely inappropriate.

Double Patenting

In the Office Action, the Examiner rejected claims 72 and 84 under the judicially created doctrine of obviousness-type double patenting over several claims from different issued patents. Specifically, the Examiner rejected claims 72 and 84 under obviousness-type double patenting over claim 9 of U.S. Patent No. 5,421,329, over claim 9 of U.S. Patent No. 5,782,237, over claims 6 and 7 of U.S. Patent No. 6,272,363, and over claim 15 of U.S. Patent No. 6,662,033.

Although Applicants do not agree with the Examiner's rejection and respectfully assert that amendments to 35 U.S.C. § 1.54 obviate the necessity of a terminal disclaimer on any claims issuing from an application claiming a priority under 35 U.S.C. § 120, Applicants submit a properly executed terminal disclaimer with the present Response. Applicants respectfully submit that the terminal disclaimer obviates the Examiner's obviousness-type double patenting rejections.

The Examiner provisionally rejected claims 72 and 84 over claim 9 of copending Application No. 11/407,771. Applicants respectfully request that the Examiner hold in

abeyance the provisional double-patenting rejection. Applicants do not believe filing a terminal disclaimer regarding copending Application No. 11/407,771 is appropriate at this time.

Conclusion

In view of the remarks set forth above, Applicants respectfully request reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

General Authorization for Extensions of Time

In accordance with 37 C.F.R. § 1.136, Applicants hereby provide a general authorization to treat this and any future reply requiring an extension of time as incorporating a request thereof. The Commissioner is authorized to charge the requisite fee of \$120 for a one month extension, the fee of \$130 for the Terminal Disclaimer, and any additional fees which may be required, to the credit card listed on the attached PTO-2038. However, if the PTO-2038 is missing, if the amount listed thereon is insufficient, or if the amount is unable to be charged to the credit card for any other reason, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0095-3 (009103-009740).

Respectfully submitted,

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